CALIFORNIA LIFE SCIENCES

Transitional Coverage for Emerging Technologies (TCET) & the *Ensuring Access to Critical Breakthrough Products Act*

Congress should pass the ***Ensuring Access to Critical Breakthrough Products Act*** **(H.R. 1691)** and encourage CMS to **finalize the TCET rule in a timely manner.**

Eliminating the Medicare Coverage Gap for Breakthrough Devices

The Breakthrough Devices Program, at the FDA, is a voluntary program for certain medical devices that provides more effective treatment options for debilitating or life-threatening conditions. It offers a significant advantage over approved, existing alternatives that are in the best interest of patients and/or fills a gap where no approved alternatives exist. While the FDA has recognized the importance of prioritizing approval of breakthrough medical devices, Medicare coverage has lagged, creating a significant barrier to patient access for these essential emerging devices. Medicare transitional coverage for breakthrough technologies would cut through the red tape to ensure access to safe, effective breakthrough medical technologies for every patient in need.

Under current policies, it takes an average of **5 years** for medical technologies to achieve nationwide coding, coverage, and payment.

Ongoing Regulatory Efforts for Expedited Medicare Coverage

On June 22, 2023, CMS publicly released its Notice on the TCET coverage pathway to establish a clear and expeditious coverage process, based on scientifically sound clinical evidence with appropriate safeguards, for emerging technologies that will benefit Medicare-eligible patients. The TCET notice is a positive incremental step forward and represents CMS' continuing commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve health and outcomes. However, the guidance does not create a new dedicated pathway for these technologies, and it excludes diagnostic tests and devices without benefit categories.

The open comment period ended on August 28, 2023, and **the rule has still not been finalized.**

The Push for a Legislative Solution

The *Ensuring Access to Critical Breakthrough Products Act* (H.R. 1691) is a legislative solution to provide automatic coverage for FDA-approved breakthrough-designated products. The bill would ensure FDA-designated breakthrough technologies are covered for four years by Medicare, and creates a roadmap for additional evidence collection for CMS to make a permanent coverage decision after that period. It would also provide a pathway for breakthrough digital technologies that are otherwise not covered by Medicare.

The bill (H.R. 1691) has **83 bipartisan cosponsors** and has seen recent **committee interest.**